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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,395	07/10/2001	Keith D. Allen	R-653	9465

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DELTAGEN, INC.
1031 Bing Street
San Carlos, CA 94070

EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,395	ALLEN, KEITH D.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-37 have been canceled. Claims 38-40 have been added and are under consideration in the instant office action.

Specification

The objection to the first line of the specification has been withdrawn.

The application numbers throughout the specification will require updating as necessary.

The objection to the description of Fig. 2A-2B has been withdrawn in view of the amendment.

Claim Rejections - 35 USC § 101

Claims 38-40 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility for reasons of record.

Claims 38 and 39 are directed toward a transgenic mouse whose genome has a homozygous disruption in an MC3-R gene with the nucleic acid sequence of SEQ ID NO:1, wherein as a result of the disruption, the mouse exhibits, relative to a wild-type mouse, passive behavior or a decrease in attempts to escape. Claim 40 is directed toward using the mouse to determine whether an agent has an effect on the passive behavior or attempts to escape.

The specification teaches making MC3-R -/- mice having only one kidney (pg 54, line 5-10). The specification suggests using the mice as a model of disease, specifically as a model for behavioral abnormalities, such as neurological, neuropsychological, psychotic phenotypes (pg 19-21; pg 21, lines 6-10). However, the specification does not disclose that behavioral abnormalities, specifically neurological, neuropsychological or psychotic disease found in humans, are linked to a disruption in MC3-R. Male MC3-R -/- mice were passive, hypoactive and did not attempt to escape during examination. Female MC3-R -/- mice were unremarkable (pg 54, lines 13-15). The specification does not provide any use for such a mouse, how such a mouse correlates to any disease, or that a disruption in MC3-R is found in hypoactive humans. None of the phenotypes described on pg 54 or claimed correlate to a useful phenotype because the phenotypes are not specific to a disease and are not linked to a disruption in an MC3-R gene in humans. The results of the tests are also not statistically significant because the number of mice tested is not disclosed. Using the mice to determine whether an agent "has an effect on the passive behavior or attempts to escape" as in claim 40 is not a specific or substantial utility because the specification does not link the phenotype to any specific disease or to a disease caused by a disruption in humans. The specification does not identify any compounds that ameliorate any condition using the mice; therefore, the asserted utility is not credible. Thus, the asserted utility of using the mice disclosed to determine whether an agent "has an effect on the passive behavior or attempts to escape" is not specific, substantial or credible.

Applicants argue the mouse can be used as a model of passive behavior. Applicants' argument is not persuasive. Passive behavior is not treated in humans. Passive behavior is not a symptom that is specific to any disease treated in humans. Therefore, the mouse claimed is not a model for any disease in humans. Tired people may be considered passive, but the mouse would not be a model for passive behavior caused by sleep deprivation. Therefore, the mouse does not adequately represent "passive behavior" in humans. The disruption in MC3-R does not represent a disruption that causes disease in humans. Therefore, the mice claimed do not represent any disease in humans. The mice cannot be used to find agonists of MC3-R because the mice do not express MC3-R. Therefore, the mice cannot be used to find drugs that modulate MC3-R. A wild-type mouse can be used to find drugs that make mice more active; therefore, the asserted utility of using mice with a disruption in SEQ ID NO:1 to find drugs that increase activity is not specific or substantial.

Applicants argue the mice can be used to determine the physiological role of MC3-R gene (pg 5, 1st paragraph of response). Applicants' argument is not persuasive. First, the mice do not express MC3-R and the function of MC3-R does not occur. Without knowing what the MC3-R gene does, the function of MC3-R may not be detectable. Second, using the mice to determine the function of MC3-R is not a substantial or credible utility because further substantial experimentation would be needed to determine the function of MC3-R. Third, the function of MC3-R may not be found using the mice. Finally, applicants do not describe determining the function MC3-R.

Regarding the phenotype of decreased attempts to escape: this phenotype has no relation to any human disease or disease symptom and is not treated in humans. Therefore, a mouse exhibiting decreased attempts to escape is in no way a model of any human disease or disease symptom.

Claim Rejections - 35 USC § 112

Claims 38-40 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use mice having a disruption in an MC3-R gene and are passive and attempt to escape less.

The rejection regarding how to make animals or cells having a disruption in an MC3-R gene other than mice has been withdrawn because the claims have been limited to mice.

The rejection regarding a correlation between the phenotype obtained in mice to the phenotype obtained in other species has been withdrawn because the claims have been limited to mice.

The rejection regarding the nexus between the disruption in MC3-R and the phenotypes claimed has been withdrawn in view of new claims.

The rejection regarding how to use a transgenic with a wild-type phenotype has been withdrawn because the mice in the new claims have non-wild-type phenotypes.

35 U.S.C. 112, second paragraph

The rejection regarding the metes and bounds of "MC3-R" genes has been withdrawn because the new claims have been limited to an MC3-R gene comprising the sequence of SEQ ID NO:1.

The rejection regarding clearly setting forth that the disruption in MC3-R causes the phenotype has been withdrawn in view of the new claims.

The rejection regarding whether the decrease in initiative ("passivity") is over a period of time or in comparison to a wild-type control has been withdrawn in view of the new claims.

The rejection regarding "hypoactivity" has been withdrawn because the new claims do not require hypoactivity.

The rejection regarding the decrease in claim 23 has been withdrawn in view of the new claims.

Claims 38-40 are newly rejected because the phrase "a decrease in attempts to escape" does not make sense. What constitutes an attempt to escape? It is unclear if the phrase is limited to any mouse that wiggles when handled or if a certain amount or force of wiggling is required to be an escape attempt. It is unclear if the phrase is limited to a mouse that runs away from the handler or if the phrase encompasses a

mouse that walks away from the handler. It is unclear if the phrase is limited to only mice that bite the handler.

Claim Rejections - 35 USC § 102

Claims 38-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Butler (Sept. 2000, Endocrinology, Vol. 141, pg 3518-3521).

The effective filing date of claims 38-40 is 10-26-00, the filing date of 60/243,958, which taught male homozygous mice were passive, hypoactive and did not attempt to escape while being handled (pg 69, last 3 lines). Provisional application 60/218,074 did not teach that the mouse was passive, hypoactive or did not attempt to escape while being handled.

Butler taught male mice with a homozygous disruption in the MC3-R gene had reduced energy expenditure as determined by reduced wheel running behavior (pg 3520, col. 1, last full ¶). Reduced wheel running is considered passive behavior as claimed. The mice taught by Butler inherently do not attempt to escape as claimed because they were made using the method described in the specification and have the same structure as the mice described in the specification, i.e. the MC3-R gene in Butler is SEQ ID NO:1 and the disruption of the MC3-R gene in Butler is the same disruption disclosed in the instant application. Therefore, the mouse of Butler inherently exhibit a decrease in attempts to escape because it has the same structure disclosed in the instant application. The wheel is "a putative agent" and determining the amount or

speed or running while on the wheel is equivalent to the "determining..." step in claim 40.

Applicants argue Butler does not teach each and every element of the claim. Specifically, applicants argue, "Butler *et al* fails to teach the specific disruption produced in the transgenic mouse, and further does not teach that the disruption results in a phenotype of passive behavior or decreased escape attempts" (pg 8 of response). Applicants' argument is not persuasive because the argument is broad and does not point to one specific element that Butler fails to teach. All of the elements claimed have been addressed in the rejection.

Claim Rejections - 35 USC § 103

The rejection under 35 U.S.C. 103(a) as being unpatentable over Huszar (Cell, Jan. 10, 1997, Vol. 88, pg 131-141) in view of Desarnaud (1994, Biochem. J., Vol. 299, pg 367-373) has been withdrawn because one of ordinary skill would not have expected the mice made to be passive or exhibit decreased attempts to escape as claimed based on the teachings of Huszar and Desarnaud.

Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler (Sept. 2000, Endocrinology, Vol. 141, pg 3518-3521) in view of Desarnaud (1994, Biochem. J., Vol. 299, pg 367-373).

The effective filing date of claims 38-40 is 10-26-00, the filing date of 60/243,958, for reasons cited above.

Butler taught male mice with a homozygous disruption in the MC3-R gene had reduced energy expenditure as determined by reduced wheel running behavior (pg 3520, col. 1, last full ¶). Reduced wheel running is considered passive behavior as claimed. The wheel is "a putative agent" and determining the amount or speed or running while on the wheel is equivalent to the "determining..." step in claim 40. Butler did not teach the MC3-R gene was SEQ ID NO:1 as claimed.

However, Desarnaud taught SEQ ID NO:1.

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to disrupt the MC3-R gene as taught by Butler, wherein the MC3-R gene had the nucleic acid sequence of SEQ ID NO:1 taught by Desarnaud. One of ordinary skill in the art at the time the invention was made would have been motivate to disrupt SEQ ID NO:1 taught by Desarnaud as the MC3-R gene taught by Butler because SEQ ID NO:1 is the MC3-R gene. One of ordinary skill in the art at the time the invention was made would have been motivate to determine if the MC3-R gene of Desarnaud had the same effect as the MC3-R gene of Butler.

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER